

510(k) Summary

K972365

Summary of the safety and effectiveness information in the premarket notification (510(k) Summary)

DEC 12 1997

Submitted by: Eurotec, srl

Address: Via Aldo Moro 5/7, 24020 Scanzorosciate (Bergamo) Italy

Telephone: (++39.35) 655-557

Contact Person: Christian Bonazzi (Official Correspondent, Technical Director of Electronic Design Department)

510(k) Number: K972365

Owner Operator ID Number: 9030797

This Summary was prepared on August 23, 1997

(1) This 510(k) summary is part of the premarket notification documentation for the unit "Compact" or "Comp-X", an X-ray mobile unit intended to be moved in a hospital or clinic or other facility to provide capability of X-ray exposures in remote areas, or in instances where stationary devices are unsuitable. Its classification name is X-ray mobile unit (RAD only). Its classification number is IZK.

(2) The device for which this 510(k) Summary is prepared is substantially equivalent to the model MU125, manufactured by Shimadzu (510(k) number: K955036). This device was found to be substantially equivalent through the 510(k) premarket notification process.

(3) The device that is subject to this 510(k) premarket notification document will be labeled on all promotional material and within all documents as "X-ray mobile unit with HF generator". The device appears as a mobile unit and is composed of three parts: The X-ray generator (monoblock) is constituted of an X-ray tube with rotating anode, encased in metal casing which also contains the high voltage generator. High voltage is required by the X-ray tube to generate a usable X-ray beam. The X-ray tube emits radiations when supplied with between 40,000 and 120,000 Volts. The monoblock is attached in a non-permanent manner to a Beam Limiting Device (BLD), which will limit the X-ray beam exiting the window of the monoblock by means of adjustable shutters. The combination of monoblock and BLD create the X-ray source.

The monoblock and the X-ray emission are controlled by an X-ray controller an electronic device connected to the monoblock through low tension cables.

X-ray generator and X-ray controller are enclosed in mechanics which allow the device to be moved on wheels, as well as the X-ray generator to be positioned as required by the operator.

The material used are metal and radiation insulating material (lead [Pb]) for the X-ray head (monoblock and BLD). The mechanics are constructed of zinc coated metal.

510(k) Summary

The device is designed to be transported on wheels: the main structure contains the electronics and sits on a triangular base with two set of wheels; two larger wheels are located at the rear of the base, while two smaller wheel (nose gear) are located at the front of the device. The top of the main structure is equipped with a column (perpendicular to the ground), which supports the arm structure; this (at the end of which is located the X-ray source) extends for 45 inches and allows vertical movements (up and down) and pivotal movements. The latter is achieved by moving the arm around its column for a total of ± 90 degrees.

The X-ray source is attached to the arm by mean of gimbals, which allow z-axis rotation and x-axis rotation for a total of ± 180 degrees each.

The BLD is also capable of movements, swiveling on its vertical axis for a total of ± 90 degrees.

The device is designed to perform X-ray exposures by means of a two-step push button (attached to the unit by mean of a 13ft coiled cord). The operator chooses the preferred setting by selecting kVp (ranging from 40 to 120) and the mAs (ranging from 0.5 to 100). After selecting the appropriate settings and positioning the device, the operator will initiate exposure by 'prepping' the exposure. This is achieved by pressing the first step of the push button. This step will feed the appropriate mA (current) to the filament of the tube, thus warming it, and will begin spinning the anode at 3000rpm. At this stage, however, there is no radiation emission, since the tube is not fed with high voltage current. Emission will begin once the unit has prepped, and will prompt (by means of a led located on the control panel) the operator to push the second step of the push-button. At this point, the current drawn from the mains and stored by capacitors will be released in one-350 Vac shot, which will be directed to the electronics and processed by an Inverter. The inverter fulfills the duty of transforming this current in High Frequency 350 Vac shot, which will be directed in this form and fed to the monoblock. This high frequency, medium-voltage current is transformed to high voltage current through a HV generator located in the monoblock. The generator will create the high voltage technique (40 to 120 kVp) set by the operator. Only after the HV reaches this point (and after all settings and parameters have been controlled and stabilized by the X-ray controller on their way to the tube) the tube emits its radiation. Radiation is emitted for a time which varies, according to the technique pre-set by the operator, between 5 milliseconds and 4 seconds.

Any problem encountered during the control by the X-ray controller, will result in an abortion of the exposure and an indication (both visual and audible) of such action.

Any exposure can also be manually aborted by the operator by releasing the push-button before the emission is terminated. This action will also result in an audible and visual signal to the operator.

After an exposure is terminated, the operator can perform another exposure after 8 to 10 seconds.

510(k) Summary

(4) INTENDED USE STATEMENT

The device is intended to be moved in a hospital or clinic or other facility to provide capability of X-ray exposures in remote areas, or in instances where stationary devices are unsuitable. The device is designed to be used in conjunction with a cassette film or other image receptor, in order to provide a radiological exposure of the human body, to serve as an aide in diagnosing illnesses and fractures. The unit is not intended to treat, prevent, cure, mitigate or otherwise medicate ailments.

(5) In brief, the device has the same technological characteristics and uses as the predicate devices stated in paragraph (2) of this Summary, in that all devices referenced in paragraph (2) are X-ray mobile units, which move on wheels, composed of a main structure, containing electronics for the control of the radiographic exposures, used within hospitals or other structures to provide capability of radiographic exposures used in the diagnosis of ailments. Furthermore, all predicate devices are furnished with an X-ray head, a high tension transformer to supply the tube with the necessary high tension, and a BLD to limit the projection of the X-ray beam as well as to give a visual indication of the area where the beam is going to be projected. These devices might, however, present some minor differences. These differences might be:

- I. kVp range: might slightly vary from device to device
- II. focal spot: might vary from device to device depending on the maximum kW output of the unit
- III. mAs range: might vary from device to device
- IV. Shortest exposure time: might vary depending on the technique settings range of a specific device
- V. motorized movements: some devices might have motorized movements in light of their weight
- VI. operating frequency: some devices might operate on low frequency, which implies a lower quality image and longer X-ray emission
- VII. mechanical movements: some devices might be equipped with mechanical movements that differ from other devices (i.e. telescopic movement of the X-ray head).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Christian Bonazzi
Official Correspondent
c/o Eurotec, srl
Via Aldo Moro 5/7
Scanzorosciate (Bergamo) 24020
Italy

Re: K972365
Compact or Comp-X (Mobile X-Ray Unit)
Dated: September 25, 1997
Received: September 26, 1997
Regulatory Class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Bonazzi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Summary

K972365

Summary of the safety and effectiveness information in the premarket notification (510(k) Summary)

DEC 12 1997

Submitted by: Eurotec, srl

Address: Via Aldo Moro 5/7, 24020 Scanzorosciate (Bergamo) Italy

Telephone: (++39.35) 655-557

Contact Person: Christian Bonazzi (Official Correspondent, Technical Director of Electronic Design Department)

510(k) Number: K972365

Owner Operator ID Number: 9030797

This Summary was prepared on August 23, 1997

(1) This 510(k) summary is part of the premarket notification documentation for the unit "Compact" or "Comp-X", an X-ray mobile unit intended to be moved in a hospital or clinic or other facility to provide capability of X-ray exposures in remote areas, or in instances where stationary devices are unsuitable. Its classification name is X-ray mobile unit (RAD only). Its classification number is IZK.

(2) The device for which this 510(k) Summary is prepared is substantially equivalent to the model MU125, manufactured by Shimadzu (510(k) number: K955036). This device was found to be substantially equivalent through the 510(k) premarket notification process.

(3) The device that is subject to this 510(k) premarket notification document will be labeled on all promotional material and within all documents as "X-ray mobile unit with HF generator". The device appears as a mobile unit and is composed of three parts: The X-ray generator (monoblock) is constituted of an X-ray tube with rotating anode, encased in metal casing which also contains the high voltage generator. High voltage is required by the X-ray tube to generate a usable X-ray beam. The X-ray tube emits radiations when supplied with between 40,000 and 120,000 Volts. The monoblock is attached in a non-permanent manner to a Beam Limiting Device (BLD), which will limit the X-ray beam exiting the window of the monoblock by means of adjustable shutters. The combination of monoblock and BLD create the X-ray source.

The monoblock and the X-ray emission are controlled by an X-ray controller an electronic device connected to the monoblock through low tension cables.

X-ray generator and X-ray controller are enclosed in mechanics which allow the device to be moved on wheels, as well as the X-ray generator to be positioned as required by the operator.

The material used are metal and radiation insulating material (lead [Pb]) for the X-ray head (monoblock and BLD). The mechanics are constructed of zinc coated metal.

510(k) Summary

The device is designed to be transported on wheels: the main structure contains the electronics and sits on a triangular base with two set of wheels; two larger wheels are located at the rear of the base, while two smaller wheel (nose gear) are located at the front of the device. The top of the main structure is equipped with a column (perpendicular to the ground), which supports the arm structure; this (at the end of which is located the X-ray source) extends for 45 inches and allows vertical movements (up and down) and pivotal movements. The latter is achieved by moving the arm around its column for a total of ± 90 degrees.

The X-ray source is attached to the arm by mean of gimbals, which allow z-axis rotation and x-axis rotation for a total of ± 180 degrees each.

The BLD is also capable of movements, swiveling on its vertical axis for a total of ± 90 degrees.

The device is designed to perform X-ray exposures by means of a two-step push button (attached to the unit by mean of a 13ft coiled cord). The operator chooses the preferred setting by selecting kVp (ranging from 40 to 120) and the mAs (ranging from 0.5 to 100). After selecting the appropriate settings and positioning the device, the operator will initiate exposure by 'prepping' the exposure. This is achieved by pressing the first step of the push button. This step will feed the appropriate mA (current) to the filament of the tube, thus warming it, and will begin spinning the anode at 3000rpm. At this stage, however, there is no radiation emission, since the tube is not fed with high voltage current. Emission will begin once the unit has prepped, and will prompt (by means of a led located on the control panel) the operator to push the second step of the push-button. At this point, the current drawn from the mains and stored by capacitors will be released in one-350 Vac shot, which will be directed to the electronics and processed by an Inverter. The inverter fulfills the duty of transforming this current in High Frequency 350 Vac shot, which will be directed in this form and fed to the monoblock. This high frequency, medium-voltage current is transformed to high voltage current through a HV generator located in the monoblock. The generator will create the high voltage technique (40 to 120 kVp) set by the operator. Only after the HV reaches this point (and after all settings and parameters have been controlled and stabilized by the X-ray controller on their way to the tube) the tube emits its radiation. Radiation is emitted for a time which varies, according to the technique pre-set by the operator, between 5 milliseconds and 4 seconds.

Any problem encountered during the control by the X-ray controller, will result in an abortion of the exposure and an indication (both visual and audible) of such action.

Any exposure can also be manually aborted by the operator by releasing the push-button before the emission is terminated. This action will also result in an audible and visual signal to the operator.

After an exposure is terminated, the operator can perform another exposure after 8 to 10 seconds.

510(k) Summary

(4) INTENDED USE STATEMENT

The device is intended to be moved in a hospital or clinic or other facility to provide capability of X-ray exposures in remote areas, or in instances where stationary devices are unsuitable. The device is designed to be used in conjunction with a cassette film or other image receptor, in order to provide a radiological exposure of the human body, to serve as an aide in diagnosing illnesses and fractures. The unit is not intended to treat, prevent, cure, mitigate or otherwise medicate ailments.

(5) In brief, the device has the same technological characteristics and uses as the predicate devices stated in paragraph (2) of this Summary, in that all devices referenced in paragraph (2) are X-ray mobile units, which move on wheels, composed of a main structure, containing electronics for the control of the radiographic exposures, used within hospitals or other structures to provide capability of radiographic exposures used in the diagnosis of ailments. Furthermore, all predicate devices are furnished with an X-ray head, a high tension transformer to supply the tube with the necessary high tension, and a BLD to limit the projection of the X-ray beam as well as to give a visual indication of the area where the beam is going to be projected. These devices might, however, present some minor differences. These differences might be:

- I. kVp range: might slightly vary from device to device
- II. focal spot: might vary from device to device depending on the maximum kW output of the unit
- III. mAs range: might vary from device to device
- IV. Shortest exposure time: might vary depending on the technique settings range of a specific device
- V. motorized movements: some devices might have motorized movements in light of their weight
- VI. operating frequency: some devices might operate on low frequency, which implies a lower quality image and longer X-ray emission
- VII. mechanical movements: some devices might be equipped with mechanical movements that differ from other devices (i.e. telescopic movement of the X-ray head).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Christian Bonazzi
Official Correspondent
c/o Eurotec, srl
Via Aldo Moro 5/7
Scanzorosciate (Bergamo) 24020
Italy

Re: K972365
Compact or Comp-X (Mobile X-Ray Unit)
Dated: September 25, 1997
Received: September 26, 1997
Regulatory Class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Bonazzi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

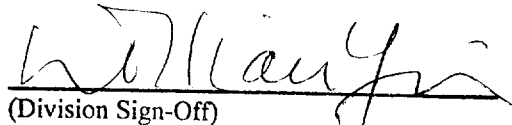
510(k) Number (if known): K972365Device Name: COMPACT or COMP-X MOBILE XRAY UNITIndications For Use: THE UNIT IS INTENDED FOR USE ON
GENERAL RADIOGRAPHIC PROCEDURES.

CHRISTIAN BONAZZI

OFFICIAL CORRESPONDENT

Bonazzi(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices510(k) Number K972365Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)